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510(k) Summary
Prepared December 16, 2011
Revised June 26, 2012

AUG 8 2012

Sponsor: NovaBay Pharmaceuticals, Inc.
5980 Horton Street
Suite 550
Emeryville, CA 94608

Contact Person: Behzad Khosrovi M.A. Ph.D.

Telephone: 510 899 8800

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Submission Date: December 16, 2011

Device Name: NeutroPhase Skin and Wound Cleanser®

Common Name: Wound Cleansing Solution

Classification:

Regulatory Class:	Unclassified
Classification Name:	Dressing, Wound, Drug
Review Code:	FRO, Unclassified
Classification Panel:	General and Plastic Surgery

A. Legally Marketed Predicate Devices

The modified device is substantially equivalent to NeutroPhase (K081009), also manufactured by NovaBay Pharmaceuticals, Inc., Vashe Wound Therapy+ Solution manufactured by PuriCore (K100918), Oculus Puracyn Antimicrobial Skin and Wound Cleanser manufactured by Oculus Innovative Sciences (K090206) and Anasept Antimicrobial Wound Cleanser (K073547), manufactured by Anacapa Technologies, Inc.

B. Device Description:

NeutroPhase Skin and Wound Cleanser is a clear, liquid solution cleanser and wound dressing that helps maintain a moist wound environment by removing dirt, debris and foreign material by the action of the skin and wound cleanser moving across the wound bed. The product is composed of HOCl 0.01% in saline. The antimicrobial agent inhibits the growth of microorganisms in solution.

C. Intended Use

NeutroPhase Skin and Wound Cleanser is intended for use under the supervision of healthcare professionals for cleansing and removal of foreign material including micro-

organisms and debris from wounds and for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, leg ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

D. Substantial Equivalence

The NeutroPhase Skin and Wound Cleanser is shown to be substantially equivalent to the predicate devices in intended use, product material composition and in method of delivery.

E. Performance Data

The modifications to the device required the following performance data: The antimicrobial activity in solution is documented by extensive testing performed by NovaBay together with additional testing by a certified test laboratory to criteria specified in USP <51>. The provision of a spray attachment to the bottle has been tested for verification of materials compatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 8 2012

NovaBay Pharmceuticals, Incorporated
% Sheila W. Pickering Consulting
Ms. Sheila W. Pickering
2081 Longden Circle
Los Altos, California 94024

Re: K113820
Trade/Device Name: NeutroPhase® Skin and Wound Cleanser
Regulation Name: Dressing, Wound, Drug
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 20, 2012
Received: July 25, 2012

Dear Ms. Pickering:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K113820 :

Device Name: NeutroPhase® Skin and Wound Cleanser

Indications for Use:

NeutroPhase Skin and Wound Cleanser is intended for use under the supervision of healthcare professionals for cleansing and removal of foreign material including micro-organisms and debris from wounds and for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, leg ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

Prescription Use _____X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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